Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089971	12/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Ba Kenosha	1801 E Kenosha St, Broken Arrow, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 12/03/2025 through 12/04/2025. The laboratory was found in compliance with standard-level deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the technical consultant, the laboratory failed to have a step-by-step procedure for one of six procedures reviewed. Findings include: (1) On 12/03/2025 at 11:45 am, the technical consultant stated the laboratory performed urine microscopic testing; (2) On 12/04

	/2025, a review of the urine microscopic procedure titled, "Saint Francis Outreach Laboratory - Urinalysis Using the Siemens Clinitek Status Siemens Multistix 10SG and Kova System" identified the procedure did not include the required speed and time to centrifuge urine specimens; (3) The procedure was reviewed with the technical consultant who stated on 12/04/2025 at 09:30 am, the procedure did not include the complete preparation of the urine specimens for microscopic analysis.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to ensure the laboratory freezer temperature was maintained as required by the manufacturer for Abbott i-Stat high sensitivity troponin I testing for 12 of 12 days from November 22, 2025 to the current date. Findings include: (1) On 12/03/2025 at 11:30 am, observation of the laboratory identified that Abbott i-Stat high sensitivity troponin I controls and calibration verification materials were stored in the laboratory freezer; (2) A review of the package insert for the Abbott i-Stat high sensitivity troponin I controls and calibration verification materials identified the manufacturer required the boxes to be stored at -20 degrees Celsius or colder; (3) A review of temperature records identified the temperature readings were greater than -20 degrees Celsius for 12 of 12 days from November 22, 2025 to the current date; (4) The records were reviewed with the technical consultant who stated on 12/03/2025 at 11:30 am, the laboratory freezer temperature had not been maintained as required by the manufacturer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant and testing person #1, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 12/03/2025 at 12:04 pm, the technical consultant and testing person #1 stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation of the laboratory on 12/03/2025 at 12:04 pm identified three inadequately labeled bottles,

	appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the technical consultant and testing person #1 who on 12/03/2025 at 12:05 pm stated the bottles contained staining materials had not been labeled with the identity, expiration date, and lot numbers.